



**Matthew Eyles**  
President and CEO

December 28, 2018

Ms. Seema Verma, Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-4185-P  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

**RE: Policy and Technical Changes to Medicare Advantage and Medicare Prescription Drug Plans for Years 2020 and 2021 ("Proposed Rule")**

Dear Administrator Verma:

America's Health Insurance Plans (AHIP) appreciates the opportunity to comment on the Proposed Rule, which would make policy and technical changes to Medicare Advantage (MA) and Medicare Prescription Drug Plans for plan years 2020 and 2021.

AHIP is the national association whose members provide coverage for health care and related services for millions of Americans. Through these offerings, including MA and Part D plans covering tens of millions of Medicare beneficiaries, we improve and protect the health and financial security for consumers, families, businesses, communities, and the nation. We are committed to market-based solutions and public-private partnerships that improve affordability, value, access, and well-being for consumers. The MA and Part D programs are critical to achieving national policy goals for improved health care, and we share your strong commitment to delivering better health outcomes, value, and satisfaction to enrollees through MA and Part D.

We strongly support steps CMS has taken to strengthen the MA program, including adding additional benefit flexibilities and reducing certain unnecessary administrative burdens. We commend CMS for following a similar approach in the Proposed Rule for implementing important legislative changes that expand access to telehealth services and enhance integration of Medicare and Medicaid benefits for individuals in dual-eligible Special Needs Plans (D-SNPs). Below we summarize our comments on these and several other provisions in the Proposed Rule. We have also attached detailed comments that discuss these and other issues.

On December 20, 2018, CMS issued new guidance that the agency will delay the original December 31 comment deadline on proposed changes related to the Risk Adjustment Data Validation (RADV) program until April 30, 2019. At the same time, CMS also indicated that the agency intends to release data underlying its study relating to the fee-for-service (FFS) adjuster. We understand that stakeholders have had pending requests for data, assumptions, and methodology disclosures. Particularly in light of this, we encourage CMS to release this information as soon as possible. A later release could endanger the public's ability to adequately analyze the data on a timely basis. We will review the information and submit extensive and detailed comments on the proposal by the new deadline.

**However, based on our review of the information and data already released by CMS, we have very serious legal and policy objections to the extrapolation and FFS adjuster proposals and strongly believe the agency should withdraw the RADV provisions in their entirety.**

If finalized as proposed by CMS, the RADV provisions would, among other things, reverse course on the need for an FFS adjuster to meet statutory and actuarial requirements and implement unprecedented regulatory changes to the MA program on a retroactive basis. These changes would inject significant uncertainty and risk into the system, undermine the partnership between Medicare and the private sector, and weaken the MA program for both seniors and taxpayers.

Extending the comment deadline and providing underlying data on the FFS adjuster study will not cure the proposed fatally-flawed approach. We recommend and urge CMS to: (1) withdraw these RADV provisions entirely; and (2) engage in direct and meaningful dialogue with MA plans and other stakeholders to develop a fair, consistent, and appropriate oversight process.

### **Policy Proposals**

As noted above, the Proposed Rule contains a number of other important changes to the MA and Part D programs, including:

**Expanded Telehealth Benefits.** CMS proposes to expand the use of telehealth in MA basic benefits, in accordance with provisions in the Bipartisan Budget Act of 2018 (BBA). We support CMS' proposed approach, which would provide plans with flexibility to design telehealth benefits to best meet the needs of Medicare enrollees and improve access to quality care. However, we recommend that CMS also provide flexibility for plan assessment of capital and infrastructure costs and investments relating to these benefits.

**D-SNP Integration and Integrated Appeals and Grievances.** CMS proposes to require certain levels of integration for D-SNPs and for D-SNPs to have aligned Medicare and Medicaid appeals and grievances processes where possible. We commend CMS for adhering closely to its statutory mandate and proposing a thoughtful approach to expand integration while limiting potential for disruption to beneficiaries and states.

**Star Ratings Changes.** We appreciate the intent of CMS' proposal to establish guardrails and use mean resampling to increase predictability and stability of the cut points for non-CAHPS measures from year to year. However, sponsors need more data to evaluate the impacts and comment on these proposed changes. We also reiterate our prior calls for the agency to reinstate predetermined cut points in advance of measurement periods. This is the best means to ensure transparency, predictability, stability, and quality improvement.

**Preclusion List Policy.** We again commend CMS for withdrawing provider and prescriber enrollment rules for MA and Part D that would have taken effect in 2019 and that would have created significant disruption and confusion for enrollees. While we generally support CMS' decision to create a new preclusion list for certain providers and prescribers, we are concerned that requirements in the Proposed Rule for 2020 would create unnecessary administrative burdens by adding new notice requirements and claims denial deadlines that deviate from the well-established approach used for the OIG exclusion list.

**Prescription Drug Plan (PDP) Access to Claims Data.** CMS proposes to establish a process for PDP sponsor access to Medicare claims data in accordance with the BBA. While we strongly support PDP access to data, the lag times proposed for the data (three-months from the last day of the prior quarter) are much too long for the data to be useful to plans. CMS can do better (e.g., it provides final claims data monthly in a bundled payment demonstration), and we believe PDPs (which do not need final claims data) should have even faster access.

### **The Value of Medicare Advantage**

MA plans provide coverage and offer meaningful value to over 20 million seniors and those with disabilities. Since 2010, Medicare beneficiaries have increasingly chosen to enroll in a MA plan rather than remain in traditional Medicare. As a result, the MA program has grown by more than 70 percent since 2010, and CMS projects that MA enrollment will represent nearly 37 percent of all beneficiaries next year. MA plans deliver better care and better value through innovative, patient-centered programs that improve quality and reduce beneficiary costs:

- **Greater care coordination and more comprehensive benefits.** MA plans work with their members to prevent, detect, and manage chronic conditions through programs that integrate and coordinate care. In addition, plans provide more comprehensive benefits than the traditional Medicare program – such as dental, hearing, and vision coverage. MA plans also can offer more extensive telehealth services and new types of supplemental benefits (e.g., home safety modifications, in-home health aides, and expanded transportation for physician visits and other medical services) recognizing the social and environmental factors that can have a profound impact on beneficiary health and outcomes.
- **More financial security.** All MA plans include a cap on beneficiary annual out-of-pocket costs, and 90 percent of beneficiaries can enroll in a MA plan that offers drug coverage for no additional premium.
- **Better health outcomes.** Recent peer-reviewed research studies have found that MA plans have outperformed the traditional Medicare program on clinical quality measures<sup>1</sup>, employed value-based payment arrangements to improve survival rates while lowering costs<sup>2</sup>, reduced hospital readmissions as well as beneficiary days spent in rehabilitation facilities and nursing homes<sup>3,4</sup>, and lowered hospital use in the last days of life.<sup>5</sup>
- **Cost efficiency for beneficiaries and taxpayers.** On average, payments to MA plans are equivalent to traditional Medicare costs.<sup>6</sup> In areas where MA is popular, additional

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<sup>1</sup> Timbie, Justin W., Bogart, Andy, Damberg, Cheryl et al. Medicare Advantage and fee-for-service performance on clinical quality and patient experience measures: Comparisons from three large states. *Health Services Research* 52(6), Part 1: 2038-2060. December 2017.

<sup>2</sup> Mandal, Alope K., Tagomori, Gene K., Felix, Randell V. et al. Value-based contracting innovated Medicare Advantage healthcare delivery and improved survival. *American Journal of Managed Care* 23(2): e41-e49. February 2017.

<sup>3</sup> Kumar, Amit, Rahman, Momotazur, Trivedi, Amal N. et al. Comparing post-acute rehabilitation use, length of stay, and outcomes experienced by Medicare fee-for-service and Medicare Advantage beneficiaries with hip fracture in the United States: A secondary analysis of administrative data. *PLoS Med* 15(6): e1002592.

<sup>4</sup> Huckfeldt, Peter J., Escarce, Jose J., Rabideau, Brendan, et al. Less intense post-acute care, better outcomes for enrollees in Medicare Advantage than those in fee-for-service. *Health Affairs* 36(1): 91-100. January 2017.

<sup>5</sup> Teno, Joan M., Gozalo, Pedro, Trivedi, Amal N. et al. Site of death, place of care, and health care transitions among US Medicare beneficiaries, 2000-2015. *JAMA* Published online June 25, 2018.

<sup>6</sup> Medicare Payment Advisory Commission. Medicare Advantage program: Status report [presentation]. December 7, 2018.

enrollment leads to slower traditional Medicare spending growth as providers use MA practice patterns and care guidelines for their remaining traditional Medicare patients.<sup>7</sup>

In addition, a recent survey finds continued high beneficiary satisfaction with the MA program, with 90 percent of MA members reporting satisfaction with their health care coverage and preventive services, and 84 percent satisfied with their prescription drug coverage.<sup>8</sup>

### **Conclusion**

We reiterate the industry's appreciation for CMS' approach in recent years of expanding flexibility and reducing administrative burdens for MA plans and commend CMS for continuing that approach in several parts of the Proposed Rule. However, we have very serious concerns with the RADV provisions and urge CMS to withdraw the proposal and begin a meaningful dialogue with industry to develop a fair and appropriate oversight process. We look forward to providing any additional information you may need and to continuing to work together to improve the health of the beneficiaries our members serve.

Sincerely,

A handwritten signature in dark ink that reads "Matthew Eyles". The signature is written in a cursive, flowing style.

Matthew Eyles  
President and CEO

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<sup>7</sup> Johnson, Garret, Figuero, Jose F., Zhou, Xiner, et al. Recent growth in Medicare Advantage enrollment associated with decreased fee-for-service spending in certain US counties. *Health Affairs* 35(9): 1707-1715. September 2016.

<sup>8</sup> Morning Consult National Poll. November 28-29, 2018.

**Medicare and Medicaid Programs; Policy and Technical Changes to the  
Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-Inclusive Care for  
the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for  
Years 2020 and 2021**

**AHIP Detailed Comments**

**I. Implementing the Bipartisan Budget Act of 2018 Provisions**

*A. Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits  
(§§422.100, 422.135, 422.252, 422.254, and 422.264, Preamble pp. 54987-54992)*

CMS proposes rules that implement section 1852(m) of the Social Security Act (SSA), as added by the Bipartisan Budget Act of 2018 (BBA). Section 1852(m) allows MA plans to provide “additional telehealth benefits” starting in plan year 2020 and to treat such benefits as basic benefits for purposes of bid submission and payment by CMS. This provision applies to services that would be covered under Medicare Part B but for the fact they are provided through electronic information and telecommunications technology (referred to as “electronic exchange”) rather than in-person.

In general, CMS proposes significant flexibility in defining the types and uses of electronic exchanges that will qualify as additional telehealth benefits. For example, MA plans could determine the circumstances under which it is clinically appropriate for a Part B item or service to be furnished through electronic exchange. CMS also proposes to permit different cost-sharing for Part B services furnished through electronic exchange compared to in-person visits.

AHIP strongly supports CMS’ approach. It would accommodate a wide variety of telehealth benefits and services and future technological advancements, consistent with legislative intent. However, we have the following recommendations to further support the flexibility needed by MA plans to design telehealth benefits to best meet the needs of Medicare enrollees and improve access to quality care.

*i. Capital and infrastructure costs and investments*

Consistent with the statutory language, the Proposed Rule excludes capital and infrastructure costs and investments relating to such benefits from amounts treated as additional telehealth benefits for bid purposes. In the preamble, CMS states that it is not providing specific definitions for capital and infrastructure costs or investments given the potential variations among MA plans. However, CMS also states in its regulatory impact analysis that the agency assumes “15 percent of the additional telehealth benefits would be considered capital and infrastructure expenses.” CMS indicates it used the administrative costs permitted under Medical Loss Ratio (MLR) rules as a proxy for the portion of telehealth benefits it assumes would be treated as capital and infrastructure costs and investments. We urge CMS to better explain the basis for this assumption. The types of additional telehealth services that will be offered and used will be wide ranging. We are concerned this 15 percent level could be viewed by CMS as a de-facto standard that will not provide individual plans the ability to demonstrate that a different level is appropriate. We recommend that the final rule specify that plans will have the flexibility to assess their own individual costs of capital and infrastructure expenses

based on the types of telehealth service benefits being provided and exclude those costs from their bids.

ii. Telehealth and network adequacy

CMS requests comments on whether additional telehealth benefit providers should be considered in the assessment of network adequacy. We strongly support such an approach. Current MA network adequacy criteria, which rely on time and distance criteria, fail to consider how telemedicine, mobile medical applications, and other electronic information and telecommunications technologies can ensure beneficiaries receive the high-quality care they need, when they need it.

We recommend that CMS provide MA plans with more flexibility in meeting network adequacy requirements through the use of telehealth providers and other high value care and delivery system innovations and approaches. In addition, CMS' 2019 MA Network Adequacy Guidance allows plans to request an exception to use telehealth providers for network adequacy but only in very limited cases such as in rural counties or areas with extreme access issues. CMS should also consider allowing more flexibility in the exceptions process. Further, where there is a shortage of providers or suppliers offering traditional Medicare benefits (e.g., under the Medicare Diabetes Prevention Program), CMS could permit use of telehealth services to better ensure access to care.

iii. Qualifications for contracted providers of additional telehealth benefits

CMS proposes to require MA plans offering additional telehealth benefits to comply with existing MA provider selection and credentialing requirements. In addition, plans would have to ensure that telehealth network providers comply with state licensing requirements and other applicable state laws where the enrollee is located and receiving the telehealth service.

CMS solicits comments on whether to impose additional qualification requirements for MA providers of additional telehealth benefits beyond those in the Proposed Rule. We strongly recommend against such an approach. We believe the proposed requirements are sufficiently protective. Given the diversity of MA plan and provider network arrangements and telehealth services, CMS should instead provide plans with the flexibility to apply their own additional network rules and conditions as they determine necessary to ensure enrollees receive high quality care.

iv. Appeals

CMS indicates in the preamble on p. 54989 that an MA enrollee has the right to request additional telehealth benefits through the organization determination and appeal processes. CMS further states that "these rights help ensure access to medically necessary services, including additional telehealth benefits offered by an MA plan as proposed in this rule."

For clarity purposes, we recommend that CMS specify in the final rule that such organization determination and appeals processes apply only to requests for telehealth services included in the MA plan's benefit package.

Finally, while not specifically addressed in the Proposed Rule, we encourage CMS to provide future guidance on issues related to additional telehealth services, including encounter data submissions. We also strongly urge CMS to establish rules under which diagnoses obtained through telehealth encounters can be considered for risk adjustment purposes, since these services will be incorporated in the MA basic benefit package starting in 2020.

*B. Dual Eligible Special Needs Plans*

- i. Integration Requirements for Dual Eligible Special Needs Plans (§§422.2, 422.60, 422.102, 422.107, 422.111, and 422.752, Preamble pp. 54992-54999)

CMS proposes several regulatory changes to implement the BBA's integration requirements for D-SNPs effective 2021. CMS delineates the three types of D-SNPs permitted by the statute and their respective responsibilities to coordinate or cover Medicare and Medicaid benefits. Furthermore, CMS proposes additional performance requirements on all D-SNPs to coordinate the delivery of benefits. States continue to retain authority for determining their Medicare-Medicaid integration environments and D-SNP options available to their dual eligible residents.

We commend CMS for the approach it has taken in the Proposed Rule, which closely adheres to the intent of the BBA. We believe the proposals will enhance Medicare-Medicaid integration with minimal disruption to states and beneficiaries by providing different pathways for states in which higher levels of integration would be challenging (such as states that exclude dually eligible individuals from Medicaid managed care).

We also support structural changes in the regulatory language, which include consolidating statutory and regulatory references and the minimum requirements for each type of D-SNP. We believe these changes should assist stakeholders, including state Medicaid agencies, in better understanding the updated SNP definitions, their respective characteristics, and implications for Medicaid program operations.

However, we believe states, D-SNPs, and other stakeholders would benefit from the following additional clarifications and examples in the requirements.

a. Arranging for benefits

Section 1859(f)(3)(D) of the SSA, which pre-dated the BBA, requires D-SNPs to provide benefits, or arrange for benefits to be provided, to which a person is entitled under Medicaid. CMS notes that it has not previously issued guidance on this requirement. CMS now proposes to interpret "arrange for benefits" as requiring that a D-SNP, at a minimum, coordinate the delivery of Medicare and Medicaid benefits. CMS proposes to include this interpretation in the proposed D-SNP definition.

While the regulatory language itself does not include specifics, the preamble notes that a D-SNP's responsibility to coordinate under this provision would encompass a wide range of activities. For example, CMS indicates that coordination for an individual with functional limitations would include verification of eligibility for specific Medicaid services like long term services and supports (LTSS), determination of how they receive services (e.g., through Medicaid FFS or Medicaid managed care),

and arrangement for receipt of services from the appropriate payer and/or provider. CMS observes that under this coordination requirement, it would not be enough for a D-SNP to simply tell an enrollee to contact a Medicaid managed care plan or the state agency without: providing specific contact information; coaching the member on the respective roles of the state Medicaid agency, the Medicaid managed care plan, and the D-SNP; and offering additional support if needed. CMS solicits comment on whether the proposed definition should be more prescriptive in identifying plan activities required for coordination or remain broadly defined.

We support the Proposed Rule's approach of broadly requiring coordination without more specific standards. This would allow states and their contracting D-SNPs a degree of flexibility in collaborating to identify specific plan activities that might differ by program or type of service. At the same time, however, prior to operationalizing this requirement, we believe states and D-SNPs would find it helpful if CMS provided clearer parameters for demonstrating sufficient coordination (e.g., through a combination of guiding principles and additional examples).

b. Notification of admissions for high risk members

CMS proposes in §422.107(d) to require that a D-SNP that is not a FIDE SNP or HIDE SNP notify the state Medicaid agency or its designee(s) of hospital and skilled nursing facility admissions for at least one group of high-risk full-benefit dual eligible individuals, as identified by the state Medicaid agency. The state Medicaid agency would also establish the timeframe(s) and method(s) by which notice would be provided.

To ensure an efficient implementation of this requirement and minimize potential uncertainty and confusion among stakeholders, we recommend that CMS provide states with technical assistance and additional guidance regarding appropriate methods, content, and timeframes for notifications. The guidance could also address specific items such as formats for data exchanges (including data feeds and portal access), plan uses of data (e.g., for determining Medicaid eligibility, identifying available waiver services, or receiving payer/payment information), and processes for designating contacts who will receive admission information. The guidance would be particularly helpful for state Medicaid programs with little experience in managed care.

In addition, the preamble to the Proposed Rule gives several examples of how high-risk full-benefit dual eligible individuals might be identified. CMS indicates processes could include, e.g., targeting groups based on eligibility for particular waiver services, or through predictive analytics of claims history. We recommend that CMS encourage states to collaborate closely with their contracted D-SNPs and Medicaid MCOs in developing criteria and processes for identifying such high-risk members.

c. Enrollment of partial dual eligibles

CMS notes that it considered proposing limits on enrollment of partial duals in D-SNPs. The agency questioned whether their continued eligibility for D-SNPs was consistent with the new statutory integration requirements, given that partial duals are eligible only for Medicaid coverage of Medicare premiums and/or cost sharing, and that there are no Medicaid services for a D-SNP to integrate or



coordinate. CMS decided against proposing such limits but continues to consider this issue and invites comments.

We support the approach in the Proposed Rule and strongly recommend that CMS continue to permit state Medicaid agencies to determine D-SNP enrollment policies for beneficiaries, including enrollment of partial dual eligibles. To the extent that a state determines it is in the interests of its partial dual eligible residents to enroll in D-SNPs, we believe that such individuals can benefit from an enhanced degree of care coordination, even if the extent of their Medicaid benefits is limited.

- ii. Unified Grievance and Appeals Procedures for Dual Eligible Special Needs Plans and Medicaid Managed Care Plans at the Plan Level (§§422.560 – 562, 422.566, 422.629 – 634, 438.210, 438.400, and 438.402, Preamble pp. 54999-55015)

CMS proposes to implement unified grievance and appeals procedures for D-SNP enrollees pursuant to SSA section 1859(f)(8)(C), as added by the BBA. The Agency proposals are in two major categories: (1) assistance that all D-SNPs must provide their members with Medicaid-related coverage issues and grievances; and (2) integrated appeals and grievances systems for exclusively aligned HIDE and FIDE SNPs.

We support CMS' overall approach in the Proposed Rule to implement the new requirements in a way that will achieve the goals of the statute while minimizing administrative complexity and burden where possible. We believe the proposals appropriately recognize that the Medicare and Medicaid statutes and benefit structures conflict too much in some cases to allow a fully unified appeals process, including post-plan appeals. Furthermore, we agree that targeted application of the rules is appropriate given the difficulty of implementing these types of procedures for plans that are not exclusively aligned.

While we support the overall approach, we believe CMS should provide the following additional clarifications and other guidance to assist stakeholders in implementing these provisions.

- a. Enrollee assistance with appeals and grievances

CMS proposes to require that all D-SNPs assist their enrollees with Medicaid coverage appeals and grievances. As with the integration requirements discussed above, we believe additional CMS guidance on several matters would help state Medicaid agencies and MA D-SNPs more efficiently interpret and apply this requirement. We recommend that CMS consider providing states and D-SNPs with technical assistance in several forms.

- + CMS should consider establishing a technical expert panel that would convene participants with backgrounds in Medicaid and Medicare appeals and grievance processes. The panel would make recommendations to CMS on appropriate practices around enrollee assistance, including guidelines for coaching enrollees on self-advocacy.
- + Based on input from the technical expert panel, CMS should develop guidance that establishes guiding principles for enrollee assistance, provides examples, and identifies related issues for states and Medicaid plans to consider. CMS should also consider

providing incentives to states to further integration. These could prove especially helpful to state Medicaid programs that have little experience with managed care.

b. Integrated notice of adverse determination

Per proposed §422.631(d)(1), CMS would require that an applicable integrated plan send an integrated notice to an enrollee when the plan issues an adverse organization determination. The proposed notice would include information about the determination, as well as information about the enrollee's appeal rights for both Medicare and Medicaid covered benefits. We request that CMS clarify whether the CMS-10003 Integrated Denial Notice meets the proposed notice requirements.

c. Interaction with appeals and grievance requirements for MMPs

In the final rule or subsequent sub-regulatory guidance, we request that CMS discuss how regulatory changes affecting appeals and grievance processes may impact or be implemented in the ongoing Medicare-Medicaid Plan (MMP) demonstrations.

*C. Proposal for Prescription Drug Plan Sponsors' Access to Medicare Parts A and B Claims Data Extracts (§423.153, Preamble pp. 55015-55017)*

CMS proposes rules to implement section 1860D-4(c)(6) of the SSA, as added by the BBA. This provision requires the agency to establish a process for a Prescription Drug Plan (PDP) sponsor to request to receive, beginning in plan year 2020, on a periodic basis and in an electronic format, standardized extracts of Medicare Part A and B claims data for its enrollees. Section 1860D-4(c)(6) also instructs the agency to include data "as current as practicable."

In its proposal, CMS would provide PDPs with Medicare claims data no sooner than on a quarterly basis with a 3-month lag from the last day of the last month of the prior quarter. We are concerned that the proposed timeframe would significantly delay access to and impact the utility of the data and is not consistent with congressional intent for providing actionable information.

We believe it is "practicable" for CMS to provide the information more frequently and promptly. For example, in the Bundled Payments for Care Improvement (BPCI) Initiative, CMS provides all participants with FFS claims files across all sites of service (i.e., inpatient and outpatient hospital, physician office, inpatient rehab, skilled nursing, home health, and durable medical equipment) on a monthly basis for each beneficiary who qualifies for a bundle under the demonstration. These files represent adjudicated (i.e., final action) claims, have at most a 1-month lag, and reflect a 14-month look back period. Participants can download these files from CMS through a unique electronic file transfer (EFT) site. In fact, we recommend that CMS should provide the data to PDPs even faster than under the BPCI demonstration, since PDPs do not require final action claims in order to use the information for care coordination and other clinical purposes.

In addition, CMS proposes to require PDPs to contractually bind contractors and any other data recipients to the terms and conditions imposed on the PDP sponsor, and to submit an attestation to the agency regarding permitted and prohibited data uses. We look forward to reviewing and

commenting on the related data request and attestation materials for PDP sponsors that CMS released through the Paperwork Reduction Act comment opportunity collection process.

## **II. Improving Program Quality and Accessibility**

- A. *Medicare Advantage and Part D Prescription Drug Plan Quality Rating System (§§422.162(a) and 423.182(a), §§422.166(a) and 423.186(a), §§422.164 and 423.184, and §§422.166(i)(1) and 423.186(i)(1), Preamble pp. 55018-55028)*

CMS proposes changes to the MA and Part D Star Ratings program affecting the cut point methodology for non-Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures, the specifications for several existing measures, and the data integrity policy related to appeals measures. The Proposed Rule also codifies requirements for calculating Star Ratings in cases of extreme and uncontrollable circumstances. Our comments and related recommendations regarding the agency's proposals are discussed below.

### i. Changes to the cut point methodology for non-CAHPS measures

Starting with 2022 Star Ratings, CMS proposes to add mean resampling to reduce the sensitivity of the clustering algorithm to outliers and reduce the random variation that contributes to fluctuation in cut points. In addition, CMS proposes to implement a 5 percent bi-directional cap that restricts movement both above and below the prior year's cut points. The bi-directional cap would be used for measures that have been in the Part C and D Star Ratings program for more than 3 years.

We appreciate CMS' willingness to consider changes to increase predictability and stability of the cut points from year to year. However, without access to simulation data and detail regarding the methodology, it is very challenging to assess and comment on the impact of CMS' proposed changes. We urge CMS to provide plans with this information as quickly as possible to permit them to conduct the needed evaluation and analysis and provide the agency with meaningful comments.

Further, AHIP continues to urge CMS to reinstate the policy that will best ensure such predictability and stability: predetermined cut points in advance of the measurement period. We believe the elimination of pre-determined thresholds has impeded CMS' goal of promoting continued quality improvement. It has undermined the ability of plans and their providers to set markers for performance activities that are consistent with CMS' expectations. Moreover, as plans have transitioned to value-based arrangements with providers, setting goals is essential to help both parties assess the effectiveness of their efforts to improve quality of care and reduce costs while maintaining high performance and rating levels. Pre-determined thresholds also provide transparency in the Star Ratings system, enabling plans and providers to understand the standards and work towards them in a deliberative process. Moreover, set cut points in advance of the measurement period would help to simplify the Star Ratings program and reduce burdens on providers contracting with multiple plans, who otherwise may face varying and conflicting quality performance metrics on the same quality measures. Predetermined cut points would thus promote a key Administration goal of reducing unnecessary regulatory burdens.

We understand CMS' concerns that the Star Rating program establish goals using more recent performance data, including large performance improvements that can be seen in newer measures, and provide continued incentives for improvement. As noted above, we believe pre-determined thresholds are the best approach to provide those incentives, and that the other positive elements (including greater transparency and simplicity and reduced burdens) far outweigh other potential concerns. Therefore, we urge CMS to issue for public comments the use of pre-determined thresholds and related methodology as soon as possible.

ii. Medicare Plan Finder (MPF) Price Accuracy measure

CMS is proposing changes to the existing MPF Price Accuracy measure for the 2022 Star Ratings. As we have indicated in previous comments, due to the frequent fluctuations in drug prices common to the pharmaceutical marketplace (which may result in changes on a weekly or even daily basis), it remains challenging for plan sponsors to ensure the MPF is updated immediately to reflect the market price of a drug. We are concerned that the proposed changes could penalize Part D plans that are continuing to make substantial investments in the accuracy of their cost reporting.

We continue to recommend that the MPF price accuracy measure be aligned with pricing practices inherent in the pharmaceutical marketplace. Further, before proposing any additional changes, CMS should clearly assess the additional value to beneficiaries of the MPF measure based on usage patterns for price data, etc., and weigh that against the costs to the program (through higher plan bids) that will arise from additional investments that may be required for Part D plans to comply with the revised methodology for this measure.

iii. Modification to data integrity policy for appeals measures

CMS proposes to assign a 1-star rating to applicable appeals measure(s) if a contract fails to submit Appeals Timeliness Monitoring Project (TMP) data for CMS' review. As we have noted in prior comments on this subject, AHIP strongly objects to Star Ratings adjustments based on compliance audit findings. This approach is highly problematic for both policy and methodological reasons. We support CMS' use of program audits to monitor plan compliance with regulatory requirements. However, the purpose and intent of the MA and Part D program audits differ significantly from those in the Star Ratings system. These audits are qualitative assessments of MA plan and Part D sponsor processes and protocols. Conversely, the Star Ratings system uses representative statistical samples from a variety of data sources to measure and compare clinical quality and beneficiary outcomes in one contract's beneficiary population with the beneficiary populations of other contracts.

We do not support CMS' proposal to modify its data integrity policy for appeals measures. CMS should ensure that the Star Ratings system is focused on improving quality of care received by beneficiaries instead of incorporating penalties on plans for compliance purposes.

iv. Codification of requirements for calculating Star Ratings in the case of extreme and uncontrollable circumstances

CMS proposes to codify rules (reflected in the 2019 Call Letter) for calculation of Star Ratings of certain contracts in certain extreme and uncontrollable circumstances (e.g., natural disasters).

AHIP supports CMS' proposal to codify such rules. At the same time, we recommend that CMS promote transparency by providing more information about the impacts of such adjustments. This can include making information publicly available on the identity of affected contracts and assessing/reporting on the impacts for the Star Ratings program both as a whole and at more granular levels, including in cases where an adjustment might span more than one measurement period.

We also note that there are important Star Ratings issues that are not addressed in the Proposed Rule that will be in the 2020 draft Call Letter, such as proposed enhancements to the Categorical Adjustment Index (CAI) methodology. AHIP supports the continued use of the CAI in the Star Ratings system while CMS develops a long-term solution to address disparities in MA plan performance associated with socio-economic status (SES) and other social risk factors. We look forward to addressing these and other important Star Ratings issues raised in the upcoming Call Letter.

*B. Improving Clarity of the Exceptions Timeframes for Part D Drugs (§§423.568, 423.570, and 423.572, Preamble pp. 55028-55029)*

CMS proposes to change the Part D adjudication timeframes for exception requests when a prescribing physician's or other prescriber's supporting statement has not been received by the plan sponsor. The current guidance lacks certainty about the timeframe applicable to the exception request process pending receipt of the prescriber's supporting statement. In the proposal, CMS would require the plan to notify the enrollee (and prescribing physician or other prescriber) of its decision no later than 72 hours (or 24 hours for an expedited decision) after receipt of the prescriber's supporting statement or 14 calendar days after receipt of the request, whichever happens first.

We support CMS' proposal. It provides plans with needed clarity on the exceptions timeframes.

### **III. Clarifying Program Integrity Policies**

*A. Preclusion List Requirements for Prescribers in Part D and Individuals and Entities in MA, Cost Plans, and PACE (§§422.222 and 423.120, Preamble pp. 55029-55037)*

CMS proposes revisions to the preclusion list policy finalized in the CY 2019 MA & Part D final rule. CMS' proposal encompasses both substantive changes to the policy and codification of provisions that were detailed in the preamble of the 2019 final rule. The substantive changes include CMS' proposal to require plans, on an ongoing monthly basis, to send a notice to potentially impacted beneficiaries within 30 days of the date a provider or prescriber is added to the preclusion list. In addition, plans would be required to deny claims for Part D drugs and MA items or services that are prescribed or furnished by prescribers and providers on the preclusion list beginning 60 days after sending the notice to the impacted beneficiary.

We appreciate CMS' efforts to reduce fraud and abuse in the Medicare program while also reducing unnecessary administrative burdens. To that end, we reiterate our strong support for CMS' decision in the 2019 final rule to remove the prescriber and provider enrollment requirements that raised serious beneficiary access issues and administrative costs. We also support CMS' general approach to implementing the preclusion list, including the agency's decision to not finalize a proposal that

would have required provisional fills for prescriptions written by prescribers on the preclusion list. However, we are concerned that CMS is now proposing changes to its preclusion list policy that would create additional complexity while providing limited value to beneficiaries.

As CMS noted in the 2019 final rule, CMS chose to not implement the provisional fill requirement for several reasons, including: the potential beneficiary confusion in taking an approach different from the exclusion list; the fact it would enable payments to be made for problematic prescribers for a long period of time, including those prescribing opioids or other potentially dangerous drugs; and the complexity and administrative burdens it would add.<sup>[1]</sup> To address these concerns, CMS indicated its goal is that “the preclusion list will be operationalized in the same manner as the OIG exclusion list ....”

We are concerned that the Proposed Rule, particularly separate required beneficiary notices and claims denial deadlines triggered by the notice, is inconsistent with this goal. We believe the proposal has the potential for causing beneficiary confusion, could enable a longer period for coverage related to problematic prescribers and providers, will present operational challenges for plans, and will increase administrative burdens.

We urge CMS not to implement this proposal. Instead, consistent with CMS’ stated intent, the preclusion list should be operationalized the same way as the OIG exclusion list. Under the exclusion list process, CMS makes the exclusion list public, updates the list on a monthly basis, generally posts it 15 days prior to the exclusion effective date, and expects plans to deny claims as of the effective date. We note that providers and prescribers are given a chance to appeal before being added to the agency’s preclusion list; therefore, we believe it would be appropriate for CMS to make the preclusion list public and implement it in the same manner as the exclusion list.

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<sup>[1]</sup> 83 Fed. Reg. 16660.